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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/335,363	06/17/1999	GEORGE SHIBATA	39D-1884	6398

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EXAMINER	
BEX, PATRICIA K	
ART UNIT	**PAPER NUMBER**
1743	17

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/335,363	SHIBATA ET AL.	
	Examiner	Art Unit	
	P. Kathryn Bex	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-11, 13-16, 20-29, 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lapeus *et al* (USP 5,720,377) and Carey *et al* (USP 5,599,501).

Lapeus *et al* teach a automated analyzer system comprising storing stations 16, 20 that receives and stores a plurality of primary sample tubes 34, a sample tube holder 38, a sampling station 32 which includes a sampling probe to transfer a volume of sample from the primary tube 34 to a secondary tube, i.e. cuvette, 84 positioned in an instrumentation device 14 as disclosed in Carey *et al,* which is incorporated therein by reference (see Lapeus *et al*, column 4, lines 56-64 and column 5, lines 18-24). Additionally, Lapeus *et al* teach a carriage mechanism 51 that grips and transports the primary tubes having a bar code to the sample identification station 83, whereby the sample tube is separated from its holder 38/38a (Fig. 2, Lapeus *et al*). The system of Carey *et al* further comprising a continuous transport mechanism 62 for moving the filled secondary tubes, i.e. cuvettes, within the system. Wherein, the continuous transport mechanism is a continuous ring, or belt 62, with a plurality of sample tube carriages 64 mounted on thereon (Fig. 2, Carey *et al*). Moreover, the system of Carey *et al* teach the use of a plurality of tube transfer stations adapted to move the secondary tubes from the continuous transport mechanism to an interface 196 of a plurality of analyzers 14 or a second different incubation chamber

(column 18, line 56- column 19, line 14). Carey *et al* teach the use of a controller 25 for receiving sample identification information and issuing a sample testing procedure such that the instrument is capable of performing different assays, each of such assays having different protocols. Lapeus *et al* teach a stat alert system for identifying when an immediate sample is loaded into the system (column 8, lines 49-65).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 17-19, 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapeus *et al* (USP 5,720,377) and Carey *et al* (USP 5,599,501) in view of Mazza *et al* (USP 5,350,564).

Lepeus *et al* teach the use of a barcode reader 83 for identifying a primary tube. Moreover, Carey *et al* do teach carriages with lateral access to the secondary sample tube by plunger 192 (Fig. 7, Carey *et al*). However, both Lapeus *et al* and Carey *et al* are silent regarding

the use of a tube spinner for holding and spinning the primary sample tube relative to the barcode reader or clips which engage the secondary sample tube when placed within the carriage. Mazza *et al* teach a automated analyzer system comprising a sample identification station for determining sample identification information, a carriage mechanism 16, 22 that transports sample tubes 28 with a bar code 30 to the sample identification station 234, a continuous transport mechanism 10 for moving the sample tubes within the system. Wherein, the continuous transport mechanism is a continuous belt 248 with a plurality of sample tube carriages 32 mounted on thereon. The sample tube carriages hold the sample tubes in place with resilient clips 258 and provide lateral access to the tube from at least two sides of the sample tube (Figs. 8-9). The system further comprising a plurality of tube transfer stations 48 adapted to move a sample tube from the continuous transport mechanism to an interface 42 of a plurality of analyzers 40, a controller "C" for receiving sample identification information and issuing a sample testing procedure (Figs. 1-10). Additionally, Mazza *et al* teach a bar code reader for reading sample identification information from the primary tube and a tube spinner for holding and spinning the primary sample tube 226, 180 (column 15, line 60- column 16, line 32). Such use of a tube spinner allows for the reader to read the bar code tag on the sample tube in the carrier regardless of where this tag may be situated on the side of the sample tube (column 15, lines 60-68).

Accordingly, it would have obvious to one of ordinary skill in the art to modify the automatic analyzer of Lepeus *et al* and Carey *et al* with those of Mazza *et al* at the time of the claimed invention. One skilled in the art would have recognized the benefits of using an tube spinner to read the bar code tag on the sample tube in the carrier, regardless of where this tag may be situated on the side of the sample tube.

Regarding the specific location of the clips within the sample tube carriage, Mazza *et al* discloses the claimed invention except for the use of clips that engage the upper and lower portion of the sample tube. It would have been an obvious matter of design choice to include such use of clips. Moreover, since applicant has not disclosed that the location of the clips solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the clips taught by Mazza *et al.*

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lapeus *et al* (USP 5,720,377) and Carey *et al* (USP 5,599,501) in view of Kurosaki *et al* (USP 5,587,129).

Lapeus *et al* and Carey *et al* as discussed previously, fail to specifically recite a sample probe comprising a cap piercer for removing liquid from the primary sample without removing the cap from the primary sample tube. However, the use of cap piercing probes is considered conventional in the art, see Kurosaki *et al.* Kurosaki *et al* teach an automatic analyzer which comprises a probe 12 for aspirating part of a sample from a sample tube 4 and dispensing into a reaction tubes 8 (column 3, line 62- column 4, line 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated in the system of Lapeus *et al* and Carey *et al* the piercing probe, as taught by Kurosaki *et al*, in order to aspirate the contents of the sample vial without exposing the sample to possible environmental contaminates.

Response to Arguments

7. Applicant's arguments filed June 17, 2002 have been fully considered but they are not persuasive. With respect to the rejection of claims 1-11, 13-16, 20-29, 33-34 under 35 U.S.C. 102(b) as being anticipated by Lapeus *et al* (USP 5,720,377) and Carey *et al* (USP

5,599,501), Applicant argues that Lapeus *et al* and Carey *et al* do not teach a carriage mechanism that grips and transports the primary sample tubes, but rather moves the primary sample tubes in their holding racks by dragging, conveying, and pushing. Examiner contends that the carriage mechanism Lapeus *et al*, comprising outwardly extending paddles or profiles 88a-b, where the sample holder 33 is positioned between them, does function to "grip" the sample holder when the belt rotates and the rack is in contact with these paddles and pushed onto the sampling station (column 7, line 50- column 8, line 26). Moreover, Examiner contends Applicant's arguments are not commensurate in scope with the claims. The specification disclose an overhead carriage and gripper assembly, the carriage is defined within the specification as the rectangular frame, or gantry, which holds the gripper 40 (page 12, lines 6-26). Examiner contends that the features upon which applicant relies (i.e., gripping means) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, the recitation of the carriage mechanism that *grips* one of the plurality of primary sample tubes is considered an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Additionally, Applicant argues that reference numerals 38/38a do not refer to the primary

tube holders, but rather the input tray which is part of the input queue. Examiner does not agree since Lapeus *et al* disclose the sample tray 38 as disposed on a housing 50 which enclosed a drive system from the rack 33, not as part of the drive system (column 6, lines 32-50). Moreover, the sample racks and tubes 34 are disclosed as being loaded onto and removed from the tray 38 without interruption of the transport system 14, therefore functioning as a "holder".

Conclusion

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
August 27, 2002

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